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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/523,503      | 03/10/2000  | Michael A. Masini    | MED-02702/29        | 4920             |

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EXAMINER

ROBERT, EDUARDO C

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 04/15/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 09/523,503             | MASINI, MICHAEL A.  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Eduardo C. Robert      | 3732                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 January 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 8-16 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 03 September 2002 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on 03 September 2002 is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 12-15 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 12, lines 3-4, applicant positively recites part of a human, i.e. "a movable member which references one of a non-prominent condyle and trochlear regions". Thus claims 12-15 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

### ***Specification***

The specification is objected to as failing to provide clear support for the claim terminology. 37 CFR § 1.75(d)(1) requires that terms and phrases used in the claims find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description. Specifically, the terms "movable member", "movable guide", "reference guide" do not appear in the specification.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 12 there exists an inconsistency between the language in the preamble and that of the body of the claim, thus making the scope of the claim unclear. In the preamble, line 1, applicant recites “Apparatus” with the non-prominent condyles separated by a trochlear region being functionally recited, i.e. “for resecting a distal femur having prominent and non-prominent condyles separated by a trochlear region...”, thus indicating that the claim is directed to the subcombination, “Apparatus”. However, in lines 3-4, applicant positively recites the non-prominent condyles and trochlear region of the distal femur as part of the invention, i.e. “a fixture including a movable member which references one of a non-prominent condyle or trochlear region...”, thus indicating that the combination, apparatus and non-prominent condyle or trochlear region, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Since claiming the combination of the apparatus and the non-prominent condyle or trochlear region makes such claim(s) directed to non-statutory subject matter, applicant should amend the claims so as to **remove all positive recitations** of the non-prominent condyle or trochlear regions. As such, the claim(s) would be directed to the subcombination, Apparatus, and will be considered as such for examination purposes.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-13, 15, and 16, **as understood**, are rejected under 35 U.S.C. 102(b) as being anticipated by Whiteside.

Whiteside discloses an apparatus comprising a fixture (see Figure 8) including a movable member 81, and a cutting guide 80. The apparatus further comprises a intramedullary rod 30 and a reference guide 82. The movable member 81 and reference guide 82 are movable along the rod 30. The apparatus also comprises a prosthesis (see Figure 23). Whiteside further discloses a method including the steps of installing the fixture onto a distal femur which references, i.e. refers to or indicate, the non-prominent condyle or trochlear region (see Figure 20) and resecting the femur in accordance with a reference or indication made by the fixture. Other steps include placing the intramedullary rod in the distal femur, moving a guide, i.e. part of the fixture, until the guide touches the non-prominent condyle or trochlear region (see Figure 20).

Claims 8-13 and 16, **as understood**, are rejected under 35 U.S.C. 102(b) as being anticipated by White.

White discloses an apparatus comprising a fixture (see Figure 1) including a movable member, and a cutting guide 113. The apparatus further comprises a intramedullary rod 37 and a reference guide 91. White further discloses a method including the steps of installing the fixture

onto a distal femur which references, i.e. refers to or indicate, the non-prominent condyle or trochlear region (see Figures 9-19) and resecting the femur in accordance with a reference or indication made by the fixture. Other steps include placing the intramedullary rod in the distal femur, moving a guide, i.e. part of the fixture, until the guide touches the non-prominent condyle or trochlear region.

***Response to Arguments***

Applicant's arguments filed on January 27, 2003 have been fully considered but they are not persuasive.

In response to applicant's argument that the human parts are not being positively recited, it is noted that applicant clearly positively recited in claim 12, one of a non-prominent condyle and trochlear regions in combination with the apparatus, i.e. "a movable member which references one of a non-prominent condyle and trochlear regions" , thus in this claims the apparatus is required to be referencing to one of the non-prominent condyle and trochlear regions, and by doing so, it includes human parts. With regard to applicant's argument that "On occasion non-statutory subject matter must be referred to in the body of a claim", it is noted that this is correct as long as it is done properly, i.e. not being positively recited or being functionally recited. With regard applicant's argument that the use of "a" as opposed to "the" overcomes the recitation of human parts, it is noted that is unclear how the use of "a" as opposed to "the" would overcome a "positive recitation" of a human part. As advised on the previous action, applicant is advised to remove all positive recitation of human parts and/or recites them functionally, e.g. using "adapted to", or "adapted for" or "for", etc.

In response to applicant's argument with regard the "clear support" for **claimed terminology**, applicant's attention is directed to the specification section above, in which the **specification** (not the disclosure) is **objected to as failing to provide clear support for the claim terminology**. 37 CFR § 1.75(d)(1) requires that terms and phrases used in the claims find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description. Specifically, the terms "movable member", "movable guide", "reference guide" do not appear in the specification. In the current case, applicant has not provide any direction or indication as to where the "specification" provided support and/or antecedent basis for the terms discussed above.

In response to applicant's argument with regard the 35 U.S.C. 112, second paragraph, rejection, applicant's attention is directed to the 35U.S.C. 112 section above in which the examiner is not arguing that the claims can not have functional language, as stated by applicant. Applicant representative should carefully re-read the 35 U.S.C. 112 section above which is directed to the ambiguity of what applicant is intent to claim and how the examiner is interpreting the claim. Moreover, applicant has not clearly stated if the claims are directed to the combination or subcombination.

In response to applicant's argument about claims be drafted in means-plus-function language, it is noted that applicant's claims are not being draft in means-plus-function language. If applicant's intention is to evoke 35 U.S.C. 112, sixth paragraph, applicant's attention is directed to MPEP 2181 which shows what applicant should meet for a claim limitation be interpreted to invoke 35 U.S.C. 112, sixth paragraph, e.g. it should meet the 3-prong analysis.

***Allowable Subject Matter***

Claim 14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

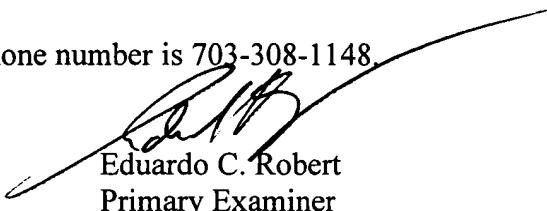
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 703-305-7333. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 703-308-2582. The fax phone numbers for the

Art Unit: 3732

organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.



Eduardo C. Robert  
Primary Examiner  
Art Unit 3732

E.C. Robert  
April 9, 2003